

Significant Legislative Rule Analysis
New Chapter 246-440 WAC
a Rule Concerning
Healthcare Associated Infections Reporting
March 20, 2014

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

This proposed rule establishes a new requirement for hospitals to report healthcare-associated *Clostridium difficile* (*C. difficile*) infections via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Net (NHSN) “LabID” event method.

Hospital infection surveillance programs already monitor *C. difficile* infections, and those participating in a Centers for Medicare and Medicaid Services (CMS) incentive program already started reporting via NHSN in January 2013. The proposed rule would make such reporting a legal requirement instead of an existing voluntary participation that offers an incentive program option.

The Department of Health (department) is proposing this rule for several reasons. First, *C. difficile* have been recognized as a growing national problem in healthcare facilities; its frequency and severity are increasing due to a new hyper virulent resistant strain that is leading to record levels of illnesses (i.e., from 2000 to 2009 the number of cases annually increased from 139,000 to 336,600, respectfully, and from 2000 to 2007 the number of annual attributed deaths increased from approximately 3,000 to 14,000, which resulted in an additional estimated \$1.3 billion in annual healthcare costs) and although prevention is difficult and challenging it is possible (McDonald LC, et al. Vital Signs: Preventing *C. difficile* Infections. MMWR 2012;61(9):157-162). Second, the department knows from Washington State death certificates that the number of deaths in which *C. difficile* is listed as a contributing cause rose year after year during the past decade. Currently the department has no active surveillance, however, to understand the frequency or severity of this disease in Washington State hospitals. Third, unless the department gains a better understanding, the department cannot offer specific advice to individual facilities about what measures they should focus on in the spectrum of prevention strategies. This spectrum includes 1) ways to identify cases and implement infection control precautions to prevent transmission from them, 2) housekeeping practices to eliminate spores from room surfaces, 3) antimicrobial stewardship to tailor use of different drugs that may decrease risk of *C. difficile* disease, and 4) methods to distinguish if this bacteria was acquired before or after hospital admission.

RCW 43.70.056 requires the department to change healthcare-associated infection reporting requirements to align state with federal requirements. Categories of federal reporting requirements are defined by the Centers for Medicare and Medicaid Services’ (CMS) Inpatient Quality Reporting voluntary financial incentive program; the reporting process for federal reporting requirements are defined by the CDC’s National Healthcare Safety Network. The

department's authority to add new reporting categories is new authority granted under an amendment to state law (House Bill 1471, Chapter 319, Laws of 2013).

Is a Significant Analysis required for this rule?

Yes, as defined in RCW 34.05.328 the proposed rule requires a significant analysis. However, the department has determined that no significant analysis is required for WAC 246-440-010, Definitions.

WAC 246-440-010 defines terms used throughout the chapter. The defined terms are incorporated, without material change, from RCW 43.70.056.

The remainder of this document will focus on those portions of the proposed rule that do require a significant analysis.

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The general goal of RCW 43.70.056 is to ensure the people of this state have hospital-specific rates of certain types of healthcare-associated infection in order to inform their health care decisions, and assurance that hospitals really are reducing the risk of preventable infections toward a goal of zero.

The statute's objectives the rule implements are:

Objective #1: Close alignment of state and federal healthcare-associated infection reporting requirements;

Objective #2: A mechanism for state government to monitor the frequency and severity of emerging healthcare-associated infection types that have the largest potential for serious illness or death.

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rule will achieve the authorizing statute's goals and objectives because it will add a federally-mandated infection reporting category to state requirements that the department considers important for protecting public health in Washington State.

The department has assessed and determined that there are no feasible alternatives to rulemaking.

If this rule is not adopted, the result would be having no mandated state-wide active monitoring process in the department to guide prevention of this serious condition.

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the proposed rule that are significant are analyzed below. As discussed above, other portions of the proposed rule are not significant and are therefore not included in this analysis.

WAC 246-440-100

Rule Overview -

This new rule satisfies a new responsibility under the 2013 revision of RCW 43.70.056 to add additional reporting requirements “when the department determines that doing so is necessary to align state reporting with the reporting categories of the CMS.” CMS added facility-wide hospital reporting of “*C. difficile* LabID Event” starting January 2013 for those participating in its Inpatient Quality Reporting (IQR) Program. The department determined that it is necessary to align state requirements with this additional reporting category.

Rule Cost/Benefit Analysis –

Department staff consulted with representatives of many hospitals to gauge the impact of the proposed reporting requirement. Respondents indicated that the cost to report is minimal. NHSN requires hospitals that report *C. difficile* LabID Event to 1) complete an annual “survey” page describing the number of patients admitted (already being done by all hospitals in our reporting network, taking approximately one hour); 2) obtain laboratory reports for *C. difficile* infection (CDI) events weekly or monthly (already being completed by hospitals in our reporting network¹, taking minimal time for the lab and the infection control professional to convey this list of “positives;” and 3) provide numbers on an NHSN website page monthly (adding CDI would take an extra minute or two over and above other reporting categories already required under state law). Most potentially affected hospitals already are in our mandatory reporting network for other infection types, so addition of *C. difficile* is likely to cause just 5-10 among the smallest hospitals to need to join the network as a new member. According to the most recent information available to us, over half the hospitals already were reporting *C. difficile* voluntarily for CMS by the 2nd quarter of 3013.

By completing the proposed actions, the immediate benefit would be that the department would have access to data about the frequency and severity of this serious type of infection and would be able to offer prevention advice depending on the current situation. Changing practices will lead to fewer infections, which will prevent morbidity and mortality. The CDC Vital Signs report cited above indicates that healthcare-associated *C. difficile* infections add \$897 million - \$1.3 billion annually to the national cost of healthcare (an excess \$5,042-\$7,179 to treat each case) and the number of associated deaths increased from 3,000 in 1999-2000 to 14,000 by 2006-2007.

¹ This task is also completed as part a hospital infection control program.

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

Descriptions of alternatives considered

NHSN currently offers participants two ways to report *C. difficile* infection: one requires review of clinical records and input of detailed information, the other requires identification of positive laboratory tests within defined periods of time relative to hospital admission and discharge. The latter, called the LabID Event option, is known to be considerably less work and is the option specified by Centers for Medicare and Medicaid quality reporting incentive program requirements.

Least burdensome determination

LabID Event Method has a low level of burden and is already used by at least 54 hospitals in 2013. The Clinical record review method has a higher level of burden. Therefore, the LabID event method is the least burdensome approach.

Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The department determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute. There are no pertinent federal statutes. The Centers for Medicare and Medicaid Services has an Inpatient Quality Reporting voluntary financial incentive program, under which those participating are required to submit specific information including *C. difficile* LabID event. The Centers for Disease Control and Prevention has specific definitions and procedures required for reporting *C. difficile* LabID event. Our proposed rule matches the CMS and CDC requirement.

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.